IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8955

Bartle, J. November 7, 2012

Emily M. Brinston ("Ms. Brinston" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Michael Brinston, Ms. Brinston's spouse, also has submitted a derivative claim for benefits.

3. Matrix benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In November, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Gregory R. Boxberger, M.D., F.A.C.C. Based on an echocardiogram dated April 10, 2002, Dr. Boxberger attested in Part II of Ms. Brinston's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of

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3. (...continued)
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1,[4] Level II Benefits.[5]

In the report of claimant's echocardiogram, the reviewing cardiologist, G. Craig Clinard, M.D., stated that claimant had "mild mitral regurgitation by color Doppler." Dr. Clinard, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Clinard also observed that "[t]he estimated [left ventricular] ejection fraction is 55-60%."[6] An ejection fraction is considered reduced for purposes of a mitral valve claim if it

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4. The Trust determined that Ms. Brinston was entitled, if at all, to Matrix B-1 benefits because the length of her Diet Drug usage was 60 days or less. See Settlement Agreement § IV.B.2.d.(2)(b). Claimant filed an appeal to arbitration with respect to this determination. Given our disposition, we will dismiss her appeal as moot.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). A reduced ejection fraction is one of the complicating factors needed to qualify for a Level II claim.

6. Claimant also submitted an echocardiogram report prepared by Dr. Boxberger in July, 2002 based on her April 10, 2002 echocardiogram. In this report Dr. Boxberger stated that claimant had "moderate mitral regurgitation, based on RJA to LAA ratio of 20%" and an "ejection fraction estimated at 55%."

is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b)iv).

In February, 2004, the Trust forwarded the claim for review by Jeremy I. Nadelmann, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Nadelmann concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild regurgitation. In support of this conclusion, Dr. Nadelmann explained that claimant "clearly has only mild [mitral regurgitation]. It extends only 1-2cm from the valve orifice and never occupies more than 10% of the LAA." In addition, Dr. Nadelmann found that there was no reasonable medical basis for finding that claimant had a reduced ejection fraction, noting that claimant had "normal [left ventricular] systolic function as the attesting cardiologist states in his [echocardiogram] report. I believe the [ejection fraction] is ~65%. If the Teicholtz calculation had been done with the [left ventricular end diastolic] and [left ventricular end systolic] dimensions it would have calculated about to ~70%."

Based on Dr. Nadelmann's findings, the Trust issued a post-audit determination denying Ms. Brinston's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[7] In

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7. Claims placed into audit on or before December 1, 2002 are (continued...)

contest, claimant submitted affidavits from Roger W. Evans, M.D., F.A.C.P., F.A.C.C.,[8] and Dan A. Francisco, M.D., F.A.C.C. In his affidavit, Dr. Evans stated that he agreed with the attesting physician that claimant had moderate mitral regurgitation with an RJA/LAA ratio of approximately 20% and a reduced ejection fraction in the range of 50% to 60%. Similarly, Dr. Francisco attested that claimant had moderate mitral regurgitation with an RJA/LAA ratio of 25%. He also noted that claimant's ejection fraction was in the range of 60% to 65% but that there was a reasonable medical basis for the attesting physician's finding of a reduced ejection fraction "[c]onsidering the expected inter-reader variability for this measurement." Claimant argued, therefore, that she had established a reasonable medical basis for her claim because three Board-Certified cardiologists agreed that she had moderate mitral regurgitation and that there was a reasonable medical basis for the attesting physician's representation of a reduced ejection fraction. Claimant further asserted that the auditing cardiologist "apparently did not understand the difference between his personal opinion ... and

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7. (...continued)
governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Brinston's claim.

8. Dr. Evans is no stranger to this litigation. According to the Trust he has signed in excess of 300 Green Forms on behalf of claimants seeking Matrix Benefits.

the 'reasonable medical basis' standard." (Emphasis in original.)

The Trust then issued a final post-audit determination, again denying Ms. Brinston's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Brinston's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5239 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 4, 2005, and claimant submitted a sur-reply on September 1, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Brinston reasserts the arguments she made in contest; namely, that the opinions of Dr. Evans and Dr. Francisco establish a reasonable medical basis for finding moderate mitral regurgitation and a reduced ejection fraction. In addition, claimant argues that the concept of inter-reader variability accounts for the differences between the opinions of claimant's physicians and those of Dr. Nadelmann.

More specifically, claimant asserts that there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, Ms. Brinston contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that the RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA ratio by an attesting physician is medically reasonable. Similarly, claimant maintains that there is also an "absolute" inter-reader variability of 18% when evaluating an ejection fraction using Simpson's Method, 16% when using wall motion index and 19% when using subjective visual assessment. If we accepted this argument, there would be a reasonable medical basis for the attesting physician's finding of an ejection fraction of 60% if the auditing cardiologist or the Technical Advisor measured the ejection fraction to be as high as 79%.

In response, the Trust argues that the opinions of Dr. Evans and Dr. Francisco are insufficient to establish a reasonable medical basis for Dr. Boxberger's Green Form representations because they "merely opine that there is a reasonable medical basis for the Attesting Physician's Green Form representations ... without addressing the Auditing Cardiologist's specific findings in audit." The Trust also notes that none of claimant's physicians address the original echocardiogram report prepared by Dr. Clinard, which indicates that Ms. Brinston had only mild mitral regurgitation. Finally, the Trust asserts that claimant's "inter-reader variability argument does not explain away Dr. Nadelmann's conclusion that

the Attesting Physician's Green Form representations of moderate mitral regurgitation and an ejection fraction of less than or equal to 60% are without any reasonable medical basis."

In her sur-reply, claimant argues that "it would be extremely unlikely that all of [claimant's] highly trained and experienced cardiologists are wrong ...." (Emphasis in original.) In addition, Ms. Brinston reiterates that the concept of inter-reader variability provides a reasonable medical basis for Dr. Boxberger's representations of moderate mitral regurgitation and a reduced ejection fraction.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Vigilante found that:

> A small jet of mitral regurgitation was noted in the parasternal long-axis view. Visually, only mild mitral regurgitation was present in the apical 4-chamber and apical two chamber views. The mitral regurgitation jet was more significant in the apical 4-chamber compared to the apical two chamber view. I digitized those cardiac cycles in the apical 4-chamber view in which the mitral regurgitation jet appeared most impressive. I then measured the RJA and LAA in these cardiac cycles. The RJA/LAA ratio was less than 15% in those views in which the mitral regurgitation jet appeared most severe. The RJA/LAA ratio never came close to approaching 20%. Most of the cardiac cycles demonstrated RJA/LAA ratios less than 10%.

Dr. Vigilante also determined that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction, stating that:

> Visually, the left ventricular ejection fraction appeared to be approximately 65% when evaluated in the parasternal long-axis, parasternal short axis, apical 4-chamber, and apical two chamber views. I digitized several cardiac cycles in the apical views in which there was excellent endocardial definition of the left ventricle. I then traced the endocardium of the left ventricle in end systole and end diastole and calculated the ejection fraction by Simpson's Rule. The ejection fraction was between 64 and 66% in these cardiac cycles. The ejection fraction never came close to 60%.

After reviewing the entire show cause record, we find claimant's arguments are without merit. First, claimant does not adequately contest the conclusions provided by the auditing cardiologist and the Technical Advisor. She does not challenge Dr. Nadelmann's determinations that claimant "clearly has only mild [mitral regurgitation]" and that ejection fraction was approximately 65%.[10] Nor does she challenge Dr. Vigilante's findings that "[m]ost of the cardiac cycles demonstrated RJA/LAA ratios less than 10%" and that claimant's ejection fraction was between 64% and 66%.[11] Although claimant submitted reports from several cardiologists, neither claimant nor her experts

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10. For this reason as well, we reject claimant's argument that the auditing cardiologist simply substituted his personal opinion for the diagnosis of the attesting physician.

11. Despite the opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

identified any specific errors in the conclusions of the auditing cardiologist and the Technical Advisor. Mere disagreement with the auditing cardiologist or the Technical Advisor without identifying any specific errors by them in insufficient to meet a claimant's burden of proof.

Claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representations that Ms. Brinston had moderate mitral regurgitation is also misplaced. The concept of inter-reader variability already is encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinions cannot be medically reasonable where the Technical Advisor concluded that claimant's echocardiogram demonstrated an RJA/LAA ratio of less than 15% in the views in which mitral regurgitation appeared most severe and the auditing cardiologist determined that the mitral regurgitant jet "extends only 1-2cm from the valve orifice and never occupies more than 10% of the LAA." Adopting claimant's argument that inter-reader variability expands the range of moderate mitral regurgitation by ±15% would allow a claimant to recover Matrix Benefits with an RJA/LAA ratio as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.[12]

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12. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement that "[a]n echocardiographer could not reasonably conclude that

(continued...)

Further, we are not persuaded by claimant's assertion that the difference in opinion regarding her ejection fraction also is due to inter-reader variability. The auditing cardiologist determined that claimant's ejection fraction was 65%. The Technical Advisor visually assessed the ejection fraction to be 65%, and using Simpson's Rule found the ejection fraction to be between 64% and 66%. If the court accepted claimant's argument of inter-reader variability, the range of moderate mitral regurgitation would be expanded by as much as ±19% and would allow a claimant to recover Matrix Benefits with an ejection fraction as high as 79%. This result would also be inconsistent with the requirements of the Settlement Agreement.[13]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation and a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Brinston's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

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12. (...continued)
moderate mitral regurgitation was present on this study even taking into account inter-reader variability."

13. In addition, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement that "[a]n echocardiographer could not reasonably conclude that an ejection fraction of 50%-60% was present on this study even taking into account inter-reader variability."